

1743 Keeping and Destroying Records
NIH Records Control Schedule

PART 4 PROTECTION FROM BIOHAZARDS, CONTAMINANTS, POLLUTANTS
AND RESEARCH RISKS CHAPTER 7000

Records accumulated in the development and implementation of standards and procedures for protection from risks, hazards and dangers stemming from biomedical research or clinical care, where NIH has broad responsibilities extending beyond NIH itself.

EXCLUDED from this section are:

Records related to protective and surveillance programs whose scope is limited to NIH or its contractors (see section 1300-B).

A. Protection of Research Subjects

Records of the Office for Protection from Research Risks.

Assurance files of statements by organizations assuring compliance with P.L. 93-348 on the protection of research subjects, human and animal, in the conduct of projects, grants and contracts supported by DHHS.

7000-A-1 Special assurance files and Single Project Assurance files for individual DHHS-supported projects, grants and contracts with supporting papers, including grant or contract application, revisions of amendments to the assurance, and related correspondence.

a. Office file.

Disposition: Place in inactive file on final payment of contract, close-out of projects or grants, or settlement of claims of litigation. Transfer each fiscal year file to Federal Records Center after 1 year in inactive file. Destroy 6 years after file is closed.

b. Other copies.

Disposition: Destroy no later than 2 years after final payment, close-out, or settlement of claims or litigation of related grant or contract.

7000-A-2 General Assurance files, Multiple Project Assurance files, Cooperative Project Assurance, Animal Welfare Assurance files, and all other OPRR Assurance Files covering DHHS-supported projects, grants or contracts of an organization.

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Included are records related to preliminary negotiations, signed assurances with revisions or amendments, related correspondence, and other supporting documents.

a. Official file.

Disposition: Place in inactive files on final payment or close-out of all projects, contracts or grants, or settlement of claims of litigation. Transfer each fiscal year file to Federal Records Center after 1 year in inactive file. Destroy 6 years after close-out.

b. Other copies.

Disposition: Destroy no later than 2 years after final payment, close-out, or settlement of claims or litigation of all contracts or grants covered by the assurance.

7000-A-3 Case files of negotiations for assurance of compliance which are withdrawn, deactivated, not approved, or not completed for other reasons.

a. Official file.

Disposition: Place in inactive file when the assurance or the related project, contract or grant is withdrawn, disapproved or otherwise inactivated. Transfer each fiscal year file to Federal Records Center after 1 year in inactive file. Destroy 6 years after file is closed..

b. Other copies.

Disposition: Destroy no later than 2 years after assurance or the related contract or grant is withdrawn, disapproved or otherwise inactivated.

7000-A-4 Cumulative List of Institutions in Compliance with policy for protection from research risks, with supporting documents.

a. Official file.

Disposition: DISPOSAL NOT AUTHORIZED. Review for disposal with NIH Records Management Officer before 1989.

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b. Other copies.

Disposition: Destroy when no longer needed for administrative reference.

7000-A-5 Inquiries and complaints of violations on research supported by DHHS involving human subjects and animal subjects.

a. Official file.

Disposition: Place in inactive file on final payment of contract, close-out of project or grant, or settlement of claims or litigation, or OPRR determination that corrective action has been implemented or is unwarranted. Transfer each fiscal year file to Federal Records Center after 1 year in inactive file. Destroy 6 years after file is closed.

b. Other copies.

Disposition: Destroy no later than 2 years after final payment close-out, or settlement of claims or litigation of related grant or contract.

7000-A-6 Reports of compliance oversight investigations and special site visits made for purposes of assuring that grantee and contractor institutions are following NIH policy for protection of research subjects and to respond to questions about the policy.

a. Official file.

Disposition: Place in inactive file on final payment of contract, close-out of project or grant, or settlement of claims or litigation or OPRR determination that corrective action has been implemented or is unwarranted. Transfer each fiscal year file to Federal Records Center after 1 year in inactive file. Destroy 6 years after file is closed.

b. Other copies.

Disposition: Destroy no later than 2 years after final payment close-out or settlement of claims or litigation of related grant or contract.

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7000-A-7 Biohazards - Protection of Research Subjects

Electronic copies created on electronic mail and word processing systems.

Disposition: Delete when file copy is generated or when referencing or updating is completed.

B. Biohazards

7000-B-1 Memoranda of understanding and agreement for use of controlled agents in research: Forms documenting the observance by NIH investigators and outside institutions of agreed upon standards governing the use of hazardous microbiological agents in either intramural or extramural research. Files include related papers.

- a. Memoranda of understanding which, in the opinion of the Assistant Director for Environmental Health and Safety or equivalent program official, may be important for future environmental or biomedical research.

Disposition: DISPOSAL NOT AUTHORIZED. Review with NIH Records Management Officer in 1988 for possible destruction.

- b. All other memoranda files.

Disposition: Destroy 5 years after completion of experiment or project.

- c. Electronic copies created on electronic mail and word processing systems.

Disposition: Delete when file copy is generated or when referencing or updating is completed.

C. Environmental Impact

7000-C-1 NIH Environmental review document and environmental statement, made in accordance with the HHS General Administration Manual, Part 30.

Disposition: DISPOSAL NOT AUTHORIZED.

7000-C-2 NIH Chemical Waste management documents, including manifest, annual report,

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permits, etc., made in conformance with the Resource Recovery and Reclamation Act of 1976 and related laws and regulations.

Disposition: DISPOSAL NOT AUTHORIZED.

7000-C-3 Environmental Impact

Electronic copies created on electronic mail and word processing systems.

Disposition: Delete when file copy is generated or when referencing or updating is completed.

D. Recombinant DNA Research (reserved)

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